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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,065	01/18/2005	W Wayne Lautt	14233.17USWO	2089

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,065	LAUTT ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-18,21-25 and 29-31* is/are pending in the application.

4a) Of the above claim(s) *7,18,22,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 8-17, 21, 23-25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants election of group II invention (claims 6-8, 11, 29 and 30) and election of N-acetylcysteine as the glutathione increasing compound and SIN-1 as the nitric oxide compound in their reply dated 8/11/06 with traverse was acknowledged. The traversal arguments were answered in the office action dated 9/11/06. Applicant's request to rejoin groups II and III was granted and claims 6-17, 21, 23, 24(in-part to the extent that the claim reads on non-insulin dependent diabetes), 25, 29-31 were examined on merit.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/07 has been entered.

Applicant's amendment to claims in the response filed on 5/3/07 has been acknowledged.

Claims 6-18, 21-25 and 29-31 are pending.

Claims 7, 18, 22, 29 and 30 have been withdrawn from further consideration as being drawn to non-elected species.

Claims 6, 8-17, 21, 23-25 and 31 are examined on the merit.

Any objections and rejections made in the previous office action not specifically mentioned here are considered withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8-17, 21, 23-25 and 31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as applied to claims 6, 8-17, 21, 23-25 and 29-31 as stated in our previous office action dated 2/5/07. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application applicants claim a pharmaceutical composition comprising a therapeutically effective amount for reducing insulin resistance of a hepatic glutathione increasing compound and a therapeutically effective amount for reducing insulin resistance of a hepatic nitric oxide-increasing compound.

Applicants argue (on page 7, paragraph 2) that claimed composition comprises a) a therapeutically effective amount for reducing insulin resistance of a hepatic glutathione-

increasing compound and b) a therapeutically effective amount for reducing insulin resistance of a hepatic nitric oxide- increasing compound. Neither the method nor the composition claim an agent that reduces insulin resistance caused by administering a hepatic NO increasing compound. Applicants respectfully assert that the Examiner has misinterpreted the claim to include a limitation that is not present.

Applicant's arguments filed 5/3/07 have been fully considered but they are not persuasive. Because, the claim 6 of the instant application as recited "A pharmaceutical composition comprising a therapeutically effective amount for reducing insulin resistance of a hepatic glutathione increasing compound and a therapeutically effective amount for reducing insulin resistance of a hepatic nitric oxide-increasing compound", imply administration of an "unknown agent" to reducing the insulin resistance of hepatic glutathione compound and insulin resistance of hepatic nitric oxide increasing compound. The recitation of the claim as "**A pharmaceutical composition comprising a therapeutically effective amount**....." imply "**A pharmaceutical composition comprising a therapeutically effective amount (of what?)**.....". The way the claim is recited clearly suggests that applicants are administering an agent to counter the effect of glutathione-increasing and nitric oxide increasing compounds. Although, the limitation of "an agent" being present in the claim as recited is not discernible, the claim as recited implies the presence of such an agent.

Further, with regards to Examiners argument that the claim as amended imply "administration of any agent to reduce insulin resistance as a result of glutathione-increasing compound and as a result of nitric oxide increasing compound", applicants argue that the claim is

not directed to the use of "agents that will reduce the insulin resistance as a result of hepatic glutathione increasing compound and hepatic NO increasing compound". Applicants further argue that the Examiner has misread the phrase "of" to mean "caused by". Applicants assert that the term "of" is used here in its common usage, a function word to indicate that the following term (e.g. "hepatic glutathione increasing compound") is qualified by the preceding term (e.g. "a therapeutically effective amount for reducing insulin resistance"). Applicants' further state that the claimed pharmaceutical composition comprises a combination of a hepatic glutathione increasing compound and a hepatic nitric oxide-increasing compound. This would be clear to the person skilled in the art having regard to the claims in isolation and in the context of the specification as a whole. Applicants point out sections of specification (see for example, page 6, lines 18-21 of the description) that discloses the use of a hepatic glutathione increasing compound together with a hepatic nitric oxide increasing compound for the treatment of insulin resistance. Applicants asserts that claim 6 further defines that each of the hepatic glutathione increasing compound and the hepatic nitric oxide increasing compounds are present in the claimed pharmaceutical composition in an amount which is therapeutically effective for reducing insulin resistance. Thus, it is clear to the skilled reader that the active agents of the claimed pharmaceutical composition are the hepatic increasing compound and the hepatic nitric compound. It is these active agents, which have the therapeutic effect of reducing insulin resistance. These active agents do not cause insulin resistance but instead prevent or treat insulin resistance. Thus, the Examiner is incorrect to assert that the amended claims imply administration of therapeutically effective amount of "any agent" for reducing insulin resistance as a result of resistance (see for example, page 6, lines 18-21 of the description). These active

agents do not cause insulin resistance but instead prevent or treat insulin resistance. Applicants state that 9 and 10 are directed to methods of treatment, which are restricted to the administration of the pharmaceutical composition of claim 6. Thus, the Examiner is incorrect to assert that the amended claims imply administration of therapeutically effective amount of "any agent" for reducing insulin resistance as a result of administering a hepatic glutathione increasing compound and "any agent" for reducing insulin resistance as a result of administering a hepatic NO increasing compound.

Applicants also argue that the Examiner allege that the specification fails to provide implicit support for agents that after insulin resistance as a result of administering glutathione increasing and NO increasing compounds are moot as the present invention is not directed to the treatment of insulin resistance caused by the administration of hepatic glutathione increasing and hepatic NO increasing compounds, but the present invention is directed to the use of hepatic glutathione increasing and hepatic NO increasing compounds as active ingredients for the treatment of insulin resistance.

Applicant's arguments filed 5/3/07 have been fully considered but they are not persuasive. Because, as mentioned earlier, the claim as recited with the term "a therapeutically effective amount" raises the question "**a therapeutically effective amount of what**?" This is because the next part of the claim recites, "**for** reducing insulin resistance of a hepatic glutathione-increasing compound" and "**for** reducing insulin resistance of a hepatic nitric oxide-increasing compound". Applicants argue that the office misread the phrase "of" to mean "caused by". As per the Cambridge dictionary of American English available on the website

"http://dictionary.cambridge.org/results.asp?dict=A&searchword=of" definition "of" has many meanings depending the context under which it is used. One of the contexts as pointed out by the applicants is "caused by" is also a definition for the phrase "of" in the cited website reference. However, applicants assert that the term "of" in the instant claim is used in its common usage, a function word to indicate that the following term (e.g. "hepatic glutathione increasing compound") is qualified by the preceding term (e.g. "a therapeutically effective amount for reducing insulin resistance") is not persuasive. Applicants have not cited any case law or provided any other reference (authority) to substantiate their argument that the claim as recited does not impart other definitions of the phrase "of" to the claim than the one applicant used to illustrate a common usage.

Although, applicants further state that the claimed pharmaceutical composition comprises a combination of a hepatic glutathione increasing compound and a hepatic nitric oxide-increasing compound by pointing out sections of specification (see for example, page 6, lines 18-21 of the description) that discloses the use of a hepatic glutathione increasing compound together with a hepatic nitric oxide increasing compound for the treatment of insulin resistance. It should be noted that claims are given the broadest interpretation in light of the supporting disclosure (see MPEP section 2106), "limitations appearing in the specification but not recited in the claims should not be read into the claims".

Applicants assertion that claim 6 further defines that each of the hepatic glutathione increasing compound and the hepatic nitric oxide increasing compounds are present in the claimed pharmaceutical composition in an amount which is therapeutically effective for reducing insulin resistance and, it is clear to the skilled reader that the active agents of the claimed

pharmaceutical composition are the hepatic glutathione-increasing compound and the hepatic nitric compound. This is not persuasive because, the claim as recited imply, that "a therapeutically effective amount of **an agent** is present in the composition **for** reducing insulin resistance of a hepatic glutathione-increasing compound and **for** reducing insulin resistance of a hepatic nitric oxide-increasing compound". A proper recitation of the claim 6 to correctly embody the applicant's assertion that the pharmaceutical composition comprising a hepatic glutathione increasing compound and a hepatic nitric oxide-increasing compound would be as follows:

A pharmaceutical composition comprising:

a) a therapeutically effective amount of hepatic glutathione increasing compound for reducing insulin resistance, and

b) a therapeutically effective amount of hepatic nitric oxide increasing compound for reducing insulin resistance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654

7/19/07
ANISH GUPTA
PRIMARY EXAMINER